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America's Opioid Crisis

Bloomberg LAW INSIGHTS

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The nation's opioid epidemic claimed more than 42,000 lives in 2016 and experts fear it will get worse before it gets better. What can be done to combat this multi-faceted threat to public health? This article looks at how the crisis began, reviews how four sectors have responded, and considers what might bring the crisis under control. The four sectors are:

• State and local government. Local officials have been dealing with rising rates of addiction and death caused by an explosion in the availability of opioids for many years. Litigation now is mushrooming as state and local governments seek to recoup their costs by suing manufacturers, distributors, pharmacies, and providers.

• Federal government. Congress is seeking to provide funding for communities in need, while the Administration is revising federal policy in Medicare, Medicaid and other programs to mitigate harm and promote treatment. Federal enforcement is expanding, increasingly relying on data-driven strategies to pursue those in the distribution chain.

• Providers and insurers. Physicians have been attempting to navigate their way through dramatic shifts in pain management practices and struggling to find the right treatment options, as insurers increasingly are monitoring prescribing patterns and applying evidence-based standards to evolving pain management and treatment practices.

• Pharmaceutical manufacturers and distributors. Companies that have made significant investments in research, development, and drug monitoring are accelerating research into alternative medications and treatments, while wrestling with an avalanche of litigation and continuing to address compliance with the regulations that govern opioid distribution.

The common theme across all four sectors is that leaders are scrambling to respond to a crisis that requires an unprecedented level of community-wide engagement and collaboration across the medical profession, justice system, pharmaceutical industry, child welfare agencies, social service agencies and the families affected by the crisis. The evolving landscape will require each sector to respond to the fast-changing nature of the crisis as those with substance use disorders migrate to the most readily available substance.

I. Genesis of the Opioid Crisis

The deaths caused by opioids in 2016 exceeded the total deaths in any single year from car accidents, gun violence and even HIV/AIDS at the height of that epidemic. Multiple factors have contributed to the crisis, including the introduction of potent, long-acting prescription pain medications. Indeed, some scholars argue that the current epidemic can be traced to the introduction of OxyContin in 1996 and acknowledged misbranding of the product by Purdue executives, accompanied by a perspective shift among physicians that such products were not necessarily as addictive as they had thought. Around the same time, patient advocates and pain societies were urging providers to take pain more seriously and treat it more aggressively, to the point that pain became the fifth vital sign in 2000. Taken together, these changes contributed to a tripling of the number of opioid prescriptions between 1999 and 2015, causing substance use disorders among many of those who took the medication as prescribed, but also a secondary market in excess pills for those prone to addiction.

To compound the crisis, heroin dealers saw an opportunity to prey upon communities overwhelmed with prescription opioids, knowing that their products were a cheaper substitute. They expanded their supply networks and deployed new technology to deliver heroin quickly, efficiently and cheaply. More recently, synthetic opioids, such as fentanyl, have contributed to the overdose and death rate, and other forms of substance abuse appear to be on the rise as well.

With growing recognition that substance use disorders are a chronic disease of the brain that require medical management, there is opportunity to move past a view that addiction represents a moral failure and to fully deploy medication assisted treatment (MAT) and other interventions unavailable in the past. Indeed, the Secretary of Health and Human Services (HHS), Alex Azar, and the Food and Drug Administration (FDA) Commissioner, Scott Gottlieb , are adding their voices to those of public health leaders who long have called for expanding MAT. However, MAT remains in short supply and often is subject to prior authorization and reauthorization requirements that deter usage.

II. State, Local, and Tribal Governments

The human toll of the crisis is most evident in those communities where addiction is prevalent and overdose deaths are commonplace. Local officials in the hardest hit communities have confronted increased costs for law enforcement and emergency care, often with limited support from state and federal officials. But that is changing as governors now are fully engaged with multi-agency task forces, outreach to community stakeholders, long lists of policy proposals, and aggressive data collection efforts. By now, most states have at least some programs designed to prevent new addictions; treat those with opioid use disorder (OUD) and support their recovery (including those cycling in and out of jail); monitor prescribing patterns; strengthen law enforcement; distribute naloxone, a medication that can reverse an otherwise fatal overdose if administered in time; and address the child welfare implications of the epidemic.

The federal government has offered some help through grants and, most significantly, Medicaid, but federal grant funding is limited and Medicaid is a state-federal partnership that requires significant state dollars. As a result, state and local officials have had to be creative, prompting them to file lawsuits against opioid manufacturers and distributors.

Civil Litigation Brought by Towns, Cities, and Tribal Governments. More than four hundred cities and counties have filed suits against opioid manufacturers, distributors, and dispensers. On December 5, 2017, the United States Judicial Panel on Multidistrict Litigation (MDL) consolidated sixty-two of these cases and transferred them to the Northern District of Ohio. (See In re National Prescription Opiate Litigation, MDL No. 2804 (Dec. 5, 2017)) Since then, more than 340 additional cases have been added to the multidistrict litigation in Ohio, with more being added nearly every week. (Id. Doc. 173) Tribal governments, whose populations have been hit hard by the crisis, have likewise entered the litigation: through March 20, 2018, a total of nine tribal entities have brought suits in courts in Oklahoma, South Dakota, Washington, California, and North Carolina.

While the cases have alleged a number of different legal theories (including negligence, nuisance, fraud, and claims under state consumer protection laws), they share common questions of fact, including whether the particular manufacturers named as defendants "overstated the benefits and downplayed the risks" of opioids, and whether distributors failed to monitor or detect "suspicious orders of prescription opiates." Indeed, most of the cases against distributors point to the Controlled Substances Act (CSA) as not having been followed, thereby violating a "duty of care." (See 21 U.S.C. § 829(e)(2)(A); 21 U.S.C. § 353(b); 21 C.F.R. § 1306.03(a)(1)) For that reason, many, if not most, of these cases will likely join the consolidated cases in the Northern District of Ohio.

Companies have raised a myriad of defenses to the state and local civil claims. In response to allegations that distributors or manufacturers have failed to meet their monitoring and reporting obligations under the CSA, companies have argued that the CSA does not provide a private right of action. In addition, defendants have claimed that a legitimate doctor's prescription necessarily breaks the chain of causation, precluding the manufacturers from being held liable for any resulting harm caused by opioids. Finally, some claims have been contested under the Free Public Services Doctrine, which limits recovery of money spent by public entities to provide services, under the theory that choosing how the government spends its money is fundamentally a legislative, not a judicial concern. The judge overseeing the consolidated cases has encouraged the parties to resolve the case, noting that during a prolonged discovery process "another 50 or 60,000 people are going to die, and we'll be absolutely no closer to abating" the crisis, and scheduled a settlement conference for May 10.

Investigations by States Attorneys General. State Attorneys General have been suing opioid manufacturers and distributors at an increased pace in recent years. (A 2004 case brought by West Virginia was quickly settled.) The current wave of cases began in 2015, with a case by Mississippi Attorney General Jim Hood; five other attorneys general have filed state-court lawsuits against manufacturers and distributors since 2015. Another 41 attorneys general collectively issued subpoenas to five manufacturers and distributors in September, 2017, but have not yet brought suit.

In late 2017, the state of Washington brought suit against Purdue Pharmaceuticals under its state consumer protection statute, a powerful tool of state prosecutors since it makes any company liable for deceptive business practices. These consumer fraud statutes generally require a materially false statement, making the accuracy of all public statements—including advertising, website materials, financial filings and public statements by executives—of paramount importance. In addition to such laws, attorneys general have relied upon common law claims for nuisance or negligence. And the Judge handling the MDL has suggested he may reach out to the attorneys general to seek their participation, stating in a hearing that "I can pick up the phone and call any state attorney general I want and invite him or them to be involved, and I'm sure they will."

The National Association of Attorneys General has taken a different approach with insurers, writing to America's Health Insurance Plans requesting that the association proactively encourage its members to "review their payment and coverage policies and revise them, as necessary and appropriate" to prioritize non-opioid treatments for chronic non-cancer pain. Allegations that insurers develop formularies that favor more addictive medications over safer alternatives have appeared in the press, and attorneys general can be expected to investigate such contentions.

Criminal Prosecutions by Local District Attorneys and State Attorneys General. Local district attorneys and State Attorneys General are stepping up criminal prosecutions of over-prescribing doctors acting in violation of the CSA. In 2016, a Los Angeles County jury found a doctor guilty of murder based on unwarranted prescription of opioids, and last July the New York State Attorney General charged a doctor with second-degree distribution of narcotics for writing fraudulent prescriptions. On March 8th, a psychiatrist was charged by the Pennsylvania Attorney General for prescribing opioids for "pain management" without being certified in pain management.

III. Federal Government

Since 2016, Congress has enacted several funding bills to fight the opioid epidemic, including $3 billion for fiscal year 2018 and an additional $3 billion for fiscal year 2019 in the recently approved budget bill. In his latest budget, President Trump called for an additional $7 billion for fiscal year 2019. While debate continues over whether such funding levels are adequate, the federal government has taken other steps to address the epidemic. The Administration declared the epidemic a public health emergency on October 26, 2017 and renewed it on January 24, 2018. Several federal agencies have initiatives underway, federal law enforcement is increasingly active on multiple fronts, and the President continues to use the bully pulpit to put forward ideas and strategies for addressing the epidemic, including during a national speech in New Hampshire on March 20, 2018. On March 21, the Attorney General issued a memo to the U.S. Attorneys encouraging them to seek capital punishment in opioid-related cases "when appropriate" under current law.

Medicare Prescription Drug Program (Part D). In 2013, the Centers for Medicare and Medicaid Services (CMS) adopted an opioid overutilization policy for its Medicare prescription drug program ("Part D") that now is being widely adopted elsewhere. The policy requires plans to deploy quantity limits and safety edits at point-of-sale for opioids, improves retrospective reviews to identify beneficiaries at high risk of overdose or abuse; establishes case management protocols for high-risk beneficiaries; and requires data-sharing among Part D plans to identify beneficiaries who may be overusing. Of particular note, CMS developed a comprehensive morphine equivalent dose (MED) approach to identifying over-utilizers, drawing on a method originally used in Washington State, as well as the opioid product list and MED conversion factors maintained by the Centers for Disease Control and Prevention (CDC). CMS recently proposed to allow Part D plans to require certain beneficiaries to obtain their opioid prescriptions from selected prescribers or pharmacies, and announced creation of an Opioid Prescription Drug Monitoring Tool that shares data on prescribing patterns to promote community awareness among providers and local officials on where issues are arising.

Medicaid. Medicaid is the largest funding source for state opioid treatment efforts, with $9.4 billion spent in fiscal year 2013. Newly-released data from three of the states hit hardest by the epidemic -- New Hampshire, Ohio and West Virginia -- documents that Medicaid contributes between 6 and 12 times as much funding for substance use disorder treatment as the Substance Abuse and Mental Health Services Administration (SAMSHA), the major source of federal grant funding for combatting the epidemic. Of particular importance has been coverage of low-income adults under the Affordable Care Act, which extended treatment to many of the people with OUD in the 32 states that have expanded Medicaid.

In light of Medicaid's critical role in the opioid epidemic, the Administration has been criticized for proposing major cuts to the program. Meanwhile, CMS continues to strengthen Medicaid's response to the epidemic, advising states in late 2017 that it would use its 1115 waiver authority to provide federal Medicaid matching funds for the cost of serving people in residential settings, including Institutions for Mental Disease. To secure such waivers, states must provide the full continuum of care for substance use disorders; deploy evidence-based practices; and report on the effectiveness of their interventions. As of March 5, 2018, 11 states have secured 1115 waivers and 9 states have pending requests.

Other federal agencies. The CDC published the CDC Guideline for Prescribing Opioids for Chronic Pain, the FDA established an Opioid Policy Steering Committee to consider strategies such as creation of a National Prescription Drug Monitoring Program (PDMP), and SAMSHA, which leads the federal government's public health response to the epidemic, has distributed grant funding to expand treatment options, encourage more health care providers to offer MAT, and reduce overdose deaths by distributing naloxone and training first responders.

Federal law enforcement. Federal law enforcement is moving aggressively to address the opioid epidemic. The Department of Justice (DOJ) and the Drug Enforcement Administration (DEA), have brought criminal and civil actions against manufacturers and distributors and "pill mill" pharmacies. The DOJ has prosecuted doctors who have written opioid prescriptions that they knew would be diverted. Since 2013, a number of retail pharmacy chains have settled civil claims for amounts ranging from $3 million to $80 million. The cases have alleged violations of the record-keeping provisions of the CSA and the regulations interpreting it. (See 21 U.S.C. § 827 and 21 C.F.R. § 1306 et seq.) DOJ has also brought criminal and civil cases against distributors and manufacturers, including C-suite defendants. One early example was a Virginia criminal misbranding case against Purdue in 2007, resulting in a $600 million guilty plea by the company and the conviction of the president, chief counsel and chief science officer. Purdue acknowledged that it was again under investigation in October 2017, this time by the U.S. Attorney for the District of Connecticut in connection with its marketing of OxyContin. That same month, the founder of another opioid manufacturer was arrested and charged with conspiracy to commit mail and wire fraud and conspiracy to violate the anti-kickback statute (AKS) by promoting off-label a fentanyl-based opioid to non-cancer patients.

Last year, the DOJ secured a $35 million civil settlement with another, manufacturer of generic opioids, for allegedly failing to report suspicious orders in violation of the CSA. A $150 million civil settlement with a distributor in July of 2017 represents the largest monetary settlement in DEA history. And grand jury subpoenas are being issued by U.S. Attorney's offices in multiple jurisdictions on multiple manufacturers. A Federal Grand Jury in the Southern District of Florida issued subpoenas to three opioid manufacturers on January 11, 2018.

Over the past eighteen months, DOJ has emphasized the role data analytics will play in such investigations. In August 2017, Attorney General Jeff Sessions established a new unit that will deploy data to identify and prosecute individuals contributing to the epidemic. The Opioid Fraud and Abuse Detection Unit assigned prosecutors to each of 12 participating federal districts. In November, he ordered every U.S. Attorney to designate an Opioid Coordinator to select cases for criminal enforcement, in part by using data analytics. In January 2018, Sessions declared that a "surge" of DEA investigators will use transaction reports to target pharmacies and prescribers that are "dispensing unusual or disproportionate amounts of drugs." And

in February 2018, Sessions announced the creation of DOJ's Prescription Interdiction & Litigation Task Force, to coordinate criminal and civil efforts and -- for the first time -- to examine pending lawsuits and determine what assistance federal intervention might provide.

The DOJ will also continue to use traditional theories of liability that it has successfully applied in non-opioid cases in the coming opioid cases. The Associate Attorney General announced that DOJ will use the False Claims Act, which "provides the government with a powerful tool to pursue all of those in the opioid distribution chain that are responsible for the improper marketing, distribution, prescription and diversion of opioids -- from pharmaceutical manufacturers to physicians, and everyone in between." DOJ has already started the process. In September 2017, DOJ settled an FCA case for $7.55 million against a biopharmaceutical company, a case brought under the traditional anti-kickback theory arising from alleged payments to doctors to ostensibly join "clinical trials" but really to prescribe opioids. Thus, manufacturers, distributors, and dispensers of opioids should be aware that the DOJ may not only investigate CSA compliance, but may also investigate marketing claims, payments to physicians, and the dispensing procedures at pharmacies. Taken together, DOJ's actions serve as a warning to all those involved in distribution of legal opioids that rigorous internal compliance, robust monitoring, and timely investigative follow-up and reporting are essential tools of the trade.

IV. Providers and Insurers

Physicians face the twin challenges of helping patients better manage chronic pain, including non-opioid and non-pharmacologic options; and treating OUD, including identifying patients on risky regimes, helping them taper to safer doses and providing access to MAT. And they must do this while managing the growing requirements of regulators and payers aimed at stemming the opioid epidemic.

State legislatures have been very active in regulating prescribing practices, with mandates to participate in PDMPs, limit opioid prescriptions, and meet new education standards. The challenge for legislators and regulators will be to avoid an over-reaction to the crisis that inhibits appropriate use of opioids or overly burdens physicians trying to balance patient needs and potential harms.

Efforts to expand treatment options have gotten less traction than new regulations because they require some combination of funding, expanded benefits, and new infrastructure. Moreover, the mind-set of harm reduction that lies at the heart of MAT is not universally accepted. Vermont has achieved some success in expanding MAT through its "hub and spoke" model that allows people to move between local spokes such as primary care offices and nine centralized hubs as their recovery needs change.

Insurers also have a major role to play helping both patients and providers change their behavior around opioid use. However, some of the tools available to insurers, such as coverage and formulary policy, can present challenges for providers and patients trying to access care. Other tools, such as education and data analysis, have a more indirect impact on behavior. Nonetheless, research conducted by the California Healthcare Foundation suggests that plans can have a meaningful impact on prescribing practices by supporting providers and patients in five areas:

• Education about alternative ways to manage pain and comparative information about opioid prescribing rates

• Benefit modifications that encourage physical therapy, behavioral health services, and complementary therapies

• Removal of preauthorization requirements for non-opioid pain medications

• Formulary changes such as dose limits, removal of dangerous formulations, and "lock" programs for patients using multiple prescribers

• Modification or removal of preauthorization requirements for buprenorphine and naloxone.

V. Pharmaceutical Manufacturers, Distributors and Pharmacy Chains

The pharmaceutical sector has been occupied developing new medications to combat the opioid epidemic, revising policies for marketing of existing pain medications, implementing appropriate monitoring to identify/prevent abuse, and responding to an overwhelming swell of litigation targeting drug manufacturers and distributors.

Proactive initiatives and remediation. In May 2017, the National Institutes of Health announced a public-private partnership designed to develop new therapies more quickly to "bring to market three types of drugs: non-addictive medications for chronic pain, better treatments for opioid addiction and improved methods of reversing opioid overdoses." Many manufacturers are dedicating significant resources to clinical development of non-addictive pain medications as well as drugs for treatment of OUD.

In February 2018, one manufacturer announced that its "sales representatives will no longer promote opioids to prescribers" and that "requests for information about our opioid products will be handled through direct communication with the highly experienced healthcare professionals that comprise our Medical Affairs department." In 2016, in response to a lawsuit by the City of Chicago, another manufacturer proactively put in place a written code of conduct for the marketing of opioids including a disclosure in promotional material warning about the risk of addiction (even when used properly) and a promise to not promote for unapproved "off label" indications such as lower back pain.

Many manufacturers are dedicating resources to clinical development of non-addictive pain medications. Two large manufacturers, for example, are collaborating on clinical development of tanezumab -- a non-opioid chronic pain medication. Several other companies are investing in clinical trials for investigational products used to treat moderate to severe pain or drugs for treatment of OUD and we anticipate other manufacturers will follow.

Knowing that timely and voluntary disclosure of wrongdoing can positively impact the course of an enforcement action, and that DOJ will consider a company's compliance and remediation efforts in making a determination of charges and penalties, companies are taking remedial actions to help lower settlement amounts. (See, e.g., United States Attorneys' Manual § 9-28.900 and § 9-28.1000). Some state attorneys general have been dissuaded from action by implementation of internal anti-diversion programs and vigorous auditing programs. A number of attorneys general, for example, wrote an open letter to one pharmacy chain praising the company for anti-diversion policies such as limiting opioid prescriptions to a seven-day supply.

More recently, a pharmacy benefit manager rolled out an enhanced opioid utilization management approach that includes strict limits on prescriptions and requiring the use of immediate-release formulations before extended-release are dispensed. Similarly, another pharmacy benefit manager launched the Advanced Opioid Management℠ program in September 2017 and reported in their 2017 Drug Trend Report a 60 percent reduction in the average days' supply per initial fill, from 18.6 days to just 7.5 days.

VI. Conclusion

The discussion above paints a picture of broad mobilization against the opioid epidemic. But where will all this activity lead? While public health experts ponder how to sustain momentum on both demand and supply-side interventions, litigants will be arguing over the genesis of the epidemic -- who is to blame and who should pay? Life science companies will say they offer vital relief to patients in severe pain and the problem is a failure to use their products appropriately. Providers will say they were following standard prescribing practices and insurers will say they were paying for prescriptions ordered by physicians. States and localities will argue that they should not be stuck financing the cost of substance abuse treatment, shoring up child welfare systems, and bolstering the criminal justice systems without help from others. And nearly everyone will be looking for the outliers that flooded communities with excess prescriptions. Meanwhile, the crisis can only be overcome if supply is reduced by enlightened law enforcement and better prescribing practices, demand is reduced by targeting environmental and individual risk factors, and outcomes are improved by supporting continued innovation in treatment and recovery support. Achieving these goals will require coordination across physical, mental health, and social services, as well as law enforcement and the justice system. It may also require significant investments in tackling the risk factors, such as social marginalization, that make fertile ground for addiction.

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